"Workshop on Evidence Based Assisted Reproductive Technologies (ART)"

Patient Advocate Perspective

Infertility Patients: Who are we?

Infertility is a disease

Infertility affects one in six people

Infertility affects men and women equally

Infertility impacts all aspects of the infertile person's life

Infertility affects people from all races and social economic levels

Infertility may not be life ending, but it can be life stopping

Pamela Madsen
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The Need For More Research: The Time Is Now

- Treating Infertility using Assisted Reproductive Technologies is a relatively young field
- Elizabeth Carr the first IVF child born in the United States is just 20 years old
- Many women who have been treated for infertility are just now reaching their “later years” when health problems can first become apparent

The Gaps in Research are Becoming Apparent

- What do we know about the children of ART?

  IVF kids?
  Special technologies such as Cryo-preservation?

  ICSI kids?
  Donor Egg Kids?
- Surprising little! WHY?
- Because the technology is so young and the kids are just now coming of age
- Funding for infertility treatment has traditionally been in the private sector with the focus on conception rather than long term follow ups

What About Me? Where Research Is Needed

- Can we separate our exposure to infertility medications from our infertility?
- Do I do better as an infertile person if I do conceive?
- What about my exposure to medications if I don't conceive?
- What is my risk of breast cancer or ovarian cancer? Is this risk raised by exposure to fertility drugs?
- Research on egg freezing
- Chemotherapy effects on fertility
- Genetic basis of inherited infertility
- Research is needed on Endometriosis

And yes, I do want to get pregnant!

- Women are starting later in their quest for a family
- Our biological clock has not kept up with our lives
- We have not solved the problem of the aging women's egg and helping women with elevated levels of FSH

What We Need To Help Us Conceive: Research!

- Fast Tracked Research

What the Doctors Say…

- Human embryo research at the fertilization and pre-implantation stages can only be performed right now if privately funded
- That probably means there is no more than $10 million a year nationwide for research
- FDA, in an attempt to safeguard the integrity of the human genome as well as the public's health, has expanded their regulations
- Regulations for tissue transplants affect many of the potential ART treatments now being investigated

What the Doctors Say…

- This regulation is stopping research which directly affects older and younger women with elevated FSH by denying possible treatment for them to use their own DNA

- If these regulations were put in place a few years ago we would not be doing egg donation or intra-cytoplasmic sperm injection (icsi)

What the Regulators Say…

- The FDA has concerns over human cells and tissues being utilized for infertility treatments
- The government is concerned about potential risks and a lack of evidence as to the effectiveness of certain new ART procedures that have been introduced into practice
- Transfer of nuclei, ooplasm, or genetic material constitutes investigational gene therapy subject to the pre-market requirements

What the Regulators Say…

- The use of genetically manipulated cells in humans requires clinical investigation and submission of an Investigational New Drug application (IND) to FDA
- Investigations would focus on applicable processing, the pre-clinical study of the safety and efficacy of the cells and the protection of human participants in clinical studies

What the Patients Say…

- As Patients we understand that, to a large extent, the fees we pay for services propel developments in reproductive technology
- As willing participants in experimental procedures, patients have the right to honest, forthright information before giving consent
- The desired information should include anticipated outcomes and possible pitfalls, what's known, and best guesses about what isn't

What the Patient Say…

- We wonder why IRB's cannot be overhauled to include a broader array of interests, patient advocates and possibly government representative among them as well as adhere to more uniform standards. This is likely to be far less intrusive and economically onerous than the creation of an entirely new system.
- If the government is committed to its current plans, we urge restraint
- We would like to know that federal guidelines will not be so cumbersome and expensive that they inhibit researchers from pursuing promising leads

What the Patients Say…

- We want to know that the costs of regulation, which are passed down to consumers, will be reasonable and contained
- Failure to contain costs will jeopardize the access to treatment for all but a very wealthy few

What the Patient Say…

- We're asking that we build on the cooperation and communications that doctors, regulators and patient advocates have already begun to build
- We're asking that, whether under the government's aegis or reconstituted IRB's, any over sight committee be composed of researchers, reproductive clinicians and patient advocates as well as regulators - to insure that politics do not interfere with my community's need for scientific breakthroughs